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| SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677 | | | EXAMINER LIN, JERRY | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/065,929

Applicant(s)

HEINE ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 29, 2007 has been entered.

Status of the Claims

Claims 1-14 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6-8, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7, which depend from claim 1, recite "the step of flagging mammograms." However, instant claim 1 only recites screening a single mammogram. It is unclear what other mammograms are being flagged. Furthermore, without the presence of a definite article such as "the" or "said" before the word "mammograms," it

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is unclear whether the "mammograms" in claims 6 and 7 even include the single mammogram recited in claim 1.

The terms "higher" and "lower" in claim 8 are relative terms, which renders the claim indefinite. The terms "higher" and "lower" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The terms "more invasive" and "less invasive" in claim 8 are relative terms, which renders the claim indefinite. The terms "more invasive" and "less invasive" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The terms "high" and "low" in claim 14 are relative terms, which renders the claim indefinite. The terms "high" and "low" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a final result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete," the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not produce a useful, concrete, and tangible final result. The useful, concrete, and tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a method of evaluating an asymptomatic patient's mammogram to identify abnormalities. However, the last step of the claims includes an

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evaluating or identifying step in the mammogram. This final step does not indicate that a result has necessarily been produced. Thus the instant claims do not require that a result must be produced. Since there is no final result in the claims, the instant claims do not include a useful, concrete, and tangible final result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5, 9, 10, 12, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305).

The instant claims are drawn to a method of screening mammograms to identify abnormalities by establishing the breast cancer risk probability value associated with an asymptomatic patient, selecting a computer algorithm to find abnormalities, determining a threshold for identifying false positives, and adjusting the threshold in response to the risk probability value, and applying the computer algorithm using the adjusted standard threshold to identify abnormalities in the patient's mammogram.

Regarding claims 1, 13 and 14, Giger et al. teach identifying a standard threshold of a computer algorithm for identifying false positive abnormalities in mammograms (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with an asymptomatic patient (column 1, line 63-column 2, line 30; column 12, line 58-column 13, line 7).

However, Giger et al. do not specifically teach calculating breast cancer risk.

Huo et al. disclose a method which includes establishing a breast cancer risk probability with a patient with factors such as age wherein the risk probability is between 0 and 1 (column 5, lines 55-63; column 6, line 25-40); applying (selecting) a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48).

Regarding claims 2 - 4, Huo et al. also discuss relative risk and absolute risk (column 3, lines 25-40) as well as include specific odds ratios in regard to breast cancer (column 3, line 66 - column 4, line 5).

Regarding claim 5, Huo et al. disclose determining parenchymal patterns (breast tissue density) (column 8, line 61-column 9, line 7; column 7, lines 18-37); integrating breast tissue density in the risk probability value (column 8, line 61-column 9, line 7; Figure 10).

Regarding claim 9, Huo et al. also disclose a data entry interface (Figure 13; column 29, lines 10-61); digitally acquiring the patient's mammogram (column 37, claim 45; column 29, lines 10-61); applying the algorithm to the mammogram (column 37, claim 45; column 29, lines 10-61).

Regarding claim 10, Huo et al. disclose storing risk factors on electronic storage medium with digitally acquire mammogram (column 37, claim 45 – column 38, claim 48; column 29, lines 10-61).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. Giger et al. indicate that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7). Based on their recommendation, one of ordinary skill in the art would have been motivated to search for a method of calculating breast cancer risk. Huo et al. provide methods of calculating breast cancer risk as well as well-known electronic means of entering and processing risk. One of ordinary skill in the art would have been motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Response to Arguments

8. The Applicants have responded to this rejection by stating that Giger et al. do not teach screening asymptomatic mammograms. The Examiner disagrees. Giger et al. teach a computer system that successfully aids the radiologist in detecting lesions and making diagnostic decisions in symptomatic or asymptomatic woman (column 1, line 63- column 2, line 30).

The Applicants also attempt to make a distinction between primary detection versus a classification scheme. However, this distinction is not found in the claims, and cannot be used to distinguish the claims from the prior art. Instant claims 1 and 14 contain the transitional language of "comprising," which indicates that the claimed invention may include more steps than the recited steps. Thus, the scope of the instant claims may include methods with classification tasks or first determining potential abnormalities in addition to the steps recited in the claims.

9. Claims 6-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305) as applied to claims 1-5, 9, 10, 12, 13 and 14 above, and further in view of Wang (US 6,266,435).

The instant claims are drawn to a method of screening mammograms to identify abnormalities by establishing the risk probability value associated with an asymptomatic patient, selecting a computer algorithm to find abnormalities, determining a threshold for identifying false positives, and adjusting the threshold in response to the risk probability

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value, and applying the computer algorithm using the adjusted standard threshold to identify abnormalities in the asymptomatic patient's mammogram. The algorithm also includes flagging mammograms (claims 6 and 7) or recommending a course of action (claim 8).

Giger et al. and Huo et al. is applied as above.

Neither Giger et al. or Huo et al. teaches flagging mammograms or recommending a course of action.

Regarding claims 6 and 7, Wang discloses flagging (marking or annotating) positive or negative results of mammograms (column 8, lines 47-65).

Regarding claim 8, based on the results of the method, the physician recommends a course of action, which would include more invasive procedures for high probability of breast cancer or less invasive procedures for low probability of breast cancer (column 2, lines 51-55).

Regarding claim 11, Wang discloses presenting the results with computer aided enhancement (column 7, lines 37-56).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. and Giger et al. with Wang to gain the benefit of electronically annotating the mammogram images. Wang discloses that his method offers the advantage of providing a physician or technician additional information to aid in the interpretation of the mammogram image as well as to aid in the determination of the best course of action for a patient (Wang, column 4, lines 1-16). Huo et al. and Giger et al. both disclose methods of interpreting digital

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mammogram images to aid physicians. Thus, one of ordinary skill in the art would have been motivated to combine the methods of Huo et al., Giger et al., and Wang to provide a complete set of tools to aid a physician in interpreting mammograms.

Response to Arguments

10. The Applicants have responded to this rejection by stating that Giger et al. does not teach the limitations in the claims. Please see above for the Examiner's response.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561.

The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.
PRIMARY EXAMINER